PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (*day/month/year*)	
Applicant's or agent's file reference 5660-01202	**IMPORTANT NOTIFICATION**

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US03/30844	29 September 2003 (30.09.2003)	30 September 2002 (30.09.2002)

Applicant

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	(Jackie) Tan-Uyen T. Ho
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5660-01202	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/30844	International filing date *(day/month/year)* 30 September 2003 (30.09.2003)	Priority date *(day/month/year)* 30 September 2002 (30.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 2/06 and US Cl.: 623/1.11, 1.23; 606/108, 194		
Applicant THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09 April 2004 (09.04.2004)	24 November 2004 (24.11.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sharon A. Greene for (Jackie) Tan-Uyen T. Ho Telephone No. (703) 308-0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30844

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-7, 10-16 as originally filed
pages NONE , filed with the demand
pages 8 and 9 , filed with the letter of 12 October 2004 (12.10.2004)

☒ the claims:
pages 10-16 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages 17-26 , filed with the letter of 12 October 2004 (12.10.2004)

☒ the drawings:
pages 1-4 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☒ the claims, Nos. 59, 60

☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/3084[redacted]

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-58	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-58	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-58	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a stent delivery system as claimed.

---------- NEW CITATIONS ----------

A portion of first conduit 12 may include a layer or coating of a material on an inner surface that facilitates insertion of instruments into the first conduit. For example, the inner surface of first conduit 12 may include a fluorine containing resin layer (e.g., TEFLON®) or other material with a low coefficient of friction.

Portions of second conduit 14 may be flexible to facilitate insertion of stent delivery system 10 into a body lumen of a patient. An outer surface of second conduit 14 may include a layer or coating of a material having a low coefficient of friction to facilitate insertion of the second conduit into the body lumen.

In some embodiments, second conduit 14 may include inner layer 38 coupled to outer layer 40. Inner layer 38 may be coupled to outer layer 40 in any way known to one skilled in the art. In certain embodiments, an opening may be formed in inner layer 38 and outer layer 40. Plug 42 may be inserted or formed in the opening to couple inner layer 38 to outer layer 40. Inner layer 38 and outer layer 40 may be formed of different materials to take advantage of different properties that may be advantageous for outer and inner surfaces of second conduit 14.

A portion of stent delivery system 10 may be sized to fit within an air passage of a patient. A cylindrical first conduit may have a diameter between about 3 mm and about 20 mm. In some embodiments, the diameter may be between about 10 mm and about 17 mm. Larger or smaller diameters may be used to accommodate specific requirements for a particular patient.

FIG. 3 depicts a cross sectional view of an embodiment of a portion of stent delivery system 10 during deployment of stent 18 in body lumen 44. Body lumen 44 depicted in FIG. 3 may be an air passageway. At least a portion of stent delivery system 10 may be positioned in body lumen 44. Endoscope 20 may be positioned in first conduit 12 prior to, or after insertion of stent delivery system 10 in body lumen 44. Endoscope 20 may include a visualization system allowing an operator direct visualization of body lumen 44 to facilitate proper placement of the distal end of stent delivery system 10 and stent 18 without the use of fluoroscopy or radioscopy. Upon properly positioning stent 18 the operator may choose to remove endoscope 20 if the operator deems it advisable to ventilate the patient. Once endoscope 20 has been removed a ventilator may be coupled to the proximal end of first conduit 12. The ability to remove endoscope 20 during a procedure is an advantage resulting directly from forming first conduit 12 from materials resistant to collapsing. The operator may also choose to allow endoscope 20 to remain in first conduit 12 for the remainder of the procedure to allow the operator to continue visually observing the deployment of stent 18.

Upon properly positioning stent 18, lock 16 may be unlocked by rotating grip 22 such that pin 26 moves from second portion 32 of opening 24 to first portion 30 of opening 24. Once lock 16 is unlocked, grip 22 may be used to retract second conduit 14 toward the proximal end of stent delivery system 10 and the operator. Indicia 36 may indicate to the operator when second conduit 14 has been retracted enough to fully expose, and therefore deploy, stent 18 (as depicted in FIG. 4). FIG. 4 depicts a cross sectional view of an embodiment of a portion of stent delivery system 10 after deployment of stent 18 in body lumen 44.

Upon deployment, a self-expanding stent will expand and lock in position within body lumen 44, other types of stents (such as balloon expandable stents) may require further manipulation at this point as described herein. Stent delivery system 10 may be removed from body lumen 44.

In some embodiments, a pulmonary stent delivery system may comprise: a first conduit; and a second conduit, wherein the first conduit is positionable in the second conduit, and wherein the first and second conduits are configurable to releasably position a stent in a body lumen during use.

In some embodiments, a pulmonary stent delivery system may comprise: a first conduit; and a second conduit, wherein the first conduit is positionable in the second conduit.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Airway assemblies may be modified to operate in other areas of a patient in which it is desired to separate a first region from a second region by a seal formed in a passage of the patient. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as examples of embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

1. A stent delivery system comprising:

a first conduit, wherein at least a portion of an endoscope is positionable in the first conduit during use;

a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent between the distal ends of the first and the second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen during use; and

a lock configurable to inhibit movement of the first conduit relative to the second conduit during use.

2. The stent delivery system of claim 1, further comprising indicia, wherein at least a portion of the indicia are visibly positioned on the proximal end of the stent delivery system during use.

3. The stent delivery system of claim 1, further comprising indicia, wherein at least a portion of the indicia are visibly positioned on the proximal end of the stent delivery system, and wherein the indicia facilitate determination of an extent of deployment of the stent during use.

4. The stent delivery system of claim 1, wherein the lock comprises a clamp.

5. The stent delivery system of claim 1, further comprising a second lock.

6. The stent delivery system of claim 1, further comprising a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use.

7. The stent delivery system of claim 1, wherein the lock comprises a ratcheted guiding system.

8. The stent delivery system of claim 1, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit; and

a second grip coupled to at least a portion of the second conduit;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

9. The stent delivery system of claim 1, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit; and

one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

10. The stent delivery system of claim 1, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit; and

one or more ratchet stops coupled to the second conduit, wherein at least one of the ratchet stops inhibits movement of the second grip relative to the second conduit in a direction toward a proximal end of the stent delivery system;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

11. The stent delivery system of claim 1, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit;

one or more ratchet stops coupled to the second conduit, wherein at least one of the ratchet stops inhibits movement of the second grip relative to the second conduit in a direction toward a proximal end of the stent delivery system; and

a separator coupled to the first grip, wherein the separator is configurable to facilitate movement of at least a portion of the second conduit beyond a distal end of the first grip;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

12. The stent delivery system of claim 1, wherein the lock comprises:

a grip coupled to at least a portion of the second conduit, wherein the first conduit is positionable in the grip;

an opening in the grip; and

a pin coupled to the first conduit, wherein the pin is positionable in the opening in the grip.

13. The stent delivery system of claim 1, wherein the lock comprises:

a grip coupled to at least a portion of the proximal end of the second conduit, wherein the first conduit is positionable in the grip;

an opening in the grip; and

a pin coupled to the first conduit, wherein the pin is positionable in the opening in the grip, and wherein the pin and opening function in combination to limit longitudinal movement to within a specified range.

14. The stent delivery system of claim 1, further comprising a stop positioned approximate the distal end of the stent delivery system between the first and second conduits.

15. The stent delivery system of claim 1, further comprising a stop positioned approximate the distal end of the stent delivery system between the first and second conduits, wherein the stop is configured to inhibit movement of the stent in a proximal direction relative to the first conduit.

16. The stent delivery system of claim 1, wherein the second conduit comprises an inner layer coupled to an outer layer.

17. The stent delivery system of claim 1, wherein the second conduit comprises an inner layer coupled to an outer layer, wherein at least the outer layer of the second conduit is coupled to a grip.

18. The stent delivery system of claim 1, wherein at least a portion of the first conduit is partially flexible.

19. The stent delivery system of claim 1, wherein at least a portion of the second conduit is partially flexible.

20. The stent delivery system of claim 1, wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit.

21. The stent delivery system of claim 1, wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit upon removal of the endoscope during use.

22. The stent delivery system of claim 1, wherein at least a portion of the second conduit is configured to inhibit collapse of the second conduit.

23. The stent delivery system of claim 1, wherein the endoscope comprises a bronchoscope, and wherein at least a portion of the bronchoscope is partially flexible.

24. The stent delivery system of claim 1, wherein the stent comprises a pulmonary stent.

25. The stent delivery system of claim 1, wherein the first conduit comprises a coiled spring.

26. The stent delivery system of claim 1, wherein the first conduit comprises a polymer.

27. The stent delivery system of claim 1, wherein the second conduit comprises a polymer.

28. The stent delivery system of claim 1, wherein the second conduit comprises TEFLON.

AMENDED SHEET

29. A stent delivery system comprising:

a first conduit, wherein at least a portion of an endoscope is positionable in the first conduit during use;

a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent between the distal ends of the first and the second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen during use; and

indicia, wherein at least a portion of the indicia are visibly positioned on the proximal end of the stent delivery system, and wherein the indicia are configurable to facilitate determination of an extent of deployment of the stent during use.

30. The stent delivery system of claim 29, further comprising:

further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use; and

a second lock.

31. The stent delivery system of claim 29, further comprising:

further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use; and

a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use.

32. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a ratcheted guiding system.

33. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit; and

a second grip coupled to at least a portion of the second conduit;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

34. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit; and

one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

35. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit; and

one or more ratchet stops coupled to the second conduit, wherein at least one of the ratchet stops inhibits movement of the second grip relative to the second conduit in a direction toward a proximal end of the stent delivery system;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

36. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a first grip coupled to at least a portion of the first conduit;

a second grip coupled to at least a portion of the second conduit;

AMENDED SHEET

one or more ratchet stops coupled to the second conduit, wherein at least one of the ratchet stops inhibits movement of the second grip relative to the second conduit in a direction toward a proximal end of the stent delivery system; and

a separator coupled to the first grip, wherein the separator is configurable to facilitate movement of at least a portion of the second conduit beyond a distal end of the first grip;

wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

37. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use.

38. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a clamp.

39. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a grip coupled to at least a portion of the second conduit, wherein the first conduit is positionable in the grip;

an opening in the grip; and

a pin coupled to the first conduit, wherein the pin is positionable in the opening in the grip.

40. The stent delivery system of claim 29, further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises:

a grip coupled to at least a portion of the proximal end of the second conduit, wherein the first conduit is positionable in the grip;

an opening in the grip; and

a pin coupled to the first conduit, wherein the pin is positionable in the opening in the grip, and wherein the pin and opening function in combination to limit longitudinal movement to within a specified range.

41. The stent delivery system of claim 29, further comprising a stop positioned approximate the distal end of the stent delivery system between the first and second conduits.

42. The stent delivery system of claim 29, further comprising a stop positioned approximate the distal end of the stent delivery system between the first and second conduits, wherein the stop is configured to inhibit movement of the stent in a proximal direction relative to the first conduit.

43. The stent delivery system of claim 29, wherein the second conduit comprises an inner layer coupled to an outer layer.

44. The stent delivery system of claim 29, wherein the second conduit comprises an inner layer coupled to an outer layer, wherein at least the outer layer of the second conduit is coupled to a grip.

45. The stent delivery system of claim 29, wherein at least a portion of the first conduit is partially flexible.

46. The stent delivery system of claim 29, wherein at least a portion of the second conduit is partially flexible.

47. The stent delivery system of claim 29, wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit.

48. The stent delivery system of claim 29, wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit upon removal of the endoscope during use.

49. The stent delivery system of claim 29, wherein at least a portion of the second conduit is configured to inhibit collapse of the second conduit.

50. The stent delivery system of claim 29, wherein the endoscope comprises a bronchoscope, and wherein the at least a portion of the bronchoscope is partially flexible.

51. The stent delivery system of claim 29, wherein the stent comprises a pulmonary stent.

52. The stent delivery system of claim 29, wherein the first conduit comprises a coiled spring.

53. The stent delivery system of claim 29, wherein the first conduit comprises a polymer.

54. The stent delivery system of claim 29, wherein the second conduit comprises a polymer.

55. The stent delivery system of claim 29, wherein the second conduit comprises TEFLON.

56. A pulmonary stent delivery system comprising:

a first conduit, wherein at least a portion of a bronchoscope is positionable in the first conduit during use;

a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of the stent between the distal ends of the first and the second conduits, and wherein the second conduit is configurable to releasably position the stent in a air passage during use.

57. A method for positioning a stent comprising:

inserting at least a portion of a stent delivery system in a body lumen;

positioning a distal end of the stent delivery system in the body lumen;

visually observing the positioning of the distal end of the stent delivery system using an endoscope positionable in a first conduit of the stent delivery system;

releasing a lock configurable to inhibit movement of the first conduit relative to a second conduit, wherein the first conduit is positionable in the second conduit; and

retracting the second conduit relative to the first conduit.

AMENDED SHEET

58. The method of claim 57, wherein retracting the second conduit relative to the first conduit comprises deploying the stent in the body lumen.